



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1182]

Joint Food and Drug Administration/Health Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of the “Joint Food and Drug Administration/Health Canada--Santé Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada.” We are making available an interpretative summary, a technical Quantitative Risk Assessment (QRA) report with appendices, a risk-assessment model, and a document responding to public comments that we received regarding the 2013 “Draft Joint Food and Drug Administration/Health Canada--Santé Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada.” The purpose of the QRA is to evaluate the effect of factors such as the microbiological status of milk, cheese-manufacturing steps, and conditions during distribution and storage on the overall risk of invasive listeriosis to the consumer of soft-ripened cheese in the United States or Canada. The QRA makes it possible to evaluate the effectiveness of some process changes and intervention strategies in reducing the risk of listeriosis.

ADDRESSES: See the SUPPLEMENTARY INFORMATION section for electronic access to the QRA and related documents.

FOR FURTHER INFORMATION CONTACT: Sherri Dennis, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1914.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the Federal Register of February 11, 2013 (78 FR 9701), we made available a document entitled “Draft Joint Food and Drug Administration/Health Canada--Santé Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada.” We gave interested parties an opportunity to submit comments by April 29, 2013, for us to consider on the approach used, the assumptions made, the modeling techniques, the data used, and the clarity and the transparency of the QRA documentation. We received nearly 100 comments on the draft QRA and have revised the QRA where appropriate (See Refs. 1 to 5).

Elsewhere in this issue of the Federal Register, we are issuing a notice requesting comments and scientific data and information that would assist us in understanding potential intervention measures to reduce the risk of foodborne illness from consumption of cheeses manufactured from unpasteurized milk.

##### II. Electronic Access

The QRA and related documents are available electronically on the FDA Web site at <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm>.

<http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>, and <http://www.regulations.gov>.

### III. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. FDA and Health Canada, “Joint Food and Drug Administration/Health Canada-Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Interpretative Summary,” 2015. Accessible at <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

2. FDA and Health Canada, “Joint Food and Drug Administration/Health Canada-Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Technical Report,” 2015. Accessible at <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

3. FDA and Health Canada, “Joint Food and Drug Administration/Health Canada-Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Technical Report Appendices,” 2015. Accessible at

<http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

4. FDA and Health Canada, “Joint Food and Drug Administration/Health Canada-Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Risk Assessment Model,” 2015. Accessible at

<http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

5. Joint FDA/Health Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Replies to Public Comments, 2015. Accessible at

<http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

Dated: July 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-18960 Filed: 7/31/2015 08:45 am; Publication Date: 8/3/2015]